

REMARKS

The above-identified patent application is directed to a method for controlled release of therapeutic, prophylactic, or diagnostic agents comprising administering to tissue in need thereof a biocompatible, polymerizable, macromer composition comprising at least one NO carrying region or NO modulating compound. Prior to this amendment, Claims 1-31 were pending in the present patent application. By this amendment, applicants cancel Claims 1-17, 19, and 25-31, which were withdrawn from consideration by the Examiner. No new claims are added. Upon current amendment, Claims 18 and 20-24 will be pending in this patent application. No new matter is introduced by the amendments. Reexamination and reconsideration of the application are requested in view of the claim amendments and the following remarks.

Objections Under 35 U.S.C. §132

The Examiner objected under 35 U.S.C. §132 to the Preliminary Amendment filed November 27, 2000, as introducing new matter into the disclosure of the invention. Applicants respectfully traverse the objection.

The Examiner objected to replacement, on pages 4 and 10, of the term “may” with the term “preferably,” asserting that, upon amendment, what was contemplated as preferable, would no longer be required. Applicants respectfully disagree with the Examiner’s assessment of the amendments as broadening the meaning of the disclosure. Common meaning of the term “preferably” is “having greater value or desirability, being preferred” (*Merriam-Webster Dictionary*, on-line edition, © 2003 by Merriam-Webster, Incorporated). Thus, the term “preferably” did not imply or confer the meaning of “required.” Therefore, what was qualified with the term “preferably,” was not required prior to the preliminary amendment, and the preliminary amendment did not cause the terms qualified with the term “preferably” to no longer be required. Hence, the preliminary amendment did not represent a

departure from the specification as filed and did not introduce any new matter into the disclosure. Accordingly, applicants respectfully request withdrawal of the objections.

Non-statutory Double Patenting Rejection

The Examiner provisionally rejected Claims 20-23 of the current patent application under the judicially created doctrine of obviousness-type double patenting as unpatentable over Claims 20-23 of co-pending U.S. Patent Application No. 10/129,418, which is commonly owned with the present patent application. To overcome the rejection, applicants will timely file a terminal disclaimer in compliance with 37 C.F.R. §1.321(c).

Claim Rejections under 35 U.S.C. §103(a)

The Examiner rejected Claims 18 and 20-24 under 35 U.S.C. §103(a) as *prima facie* obvious over *Roth et al.* (U.S. Patent No. 5,879,713) in view of *Trescony et al.* (U.S. Patent No. 5,994,444). Applicants respectfully traverse the rejection.

Roth et al. teaches a polymeric material for delivery of biologically active molecules, wherein the hydrogel is used to entrap and homogeneously disperse the biologically active molecules for release after polymerization of the hydrogel. *Trescony et al.* teaches a polymeric materials impregnated with a nitric oxide donor for continuous release of nitric oxide upon hydration of the material. Both *Roth et al.* and *Trescony et al.* teach incorporation of biologically active molecules into the polymeric material by entrapment (column 5, lines 13-15, 22-23, and 30-36 in *Roth et al.*), dispersion, or embedding (column 5, lines 35-39, column 6, lines 6-7 and 32-34 in *Trescony et al.*).

In contrast, the applicants' invention as claimed uses a macromer composition comprising at least one NO carrying region or NO modulating compound. Thus, applicants' macromer molecules include chemical groups, to which NO molecules or NO modulating molecules are complexed. *Roth et al.* and *Trescony et al.*, alone or in combination, fail to teach, suggest, or provide motivation to use polymeric materials comprising chemical groups

to which NO molecules or NO modulating molecules are complexed. Thus, the cited publications fail to teach an element of the applicants' invention as claimed.

The incorporation of the biologically active molecules in *Roth et al.* and *Trescony et al.* is dependent on the ability of the polymeric material to entrap the biologically active molecules in its pores. This limits the biologically active molecules to large molecules, or necessitates incorporation of the biologically active molecules or their carriers in a particulate form (column 9, line 59, through column 10, line 27, in *Roth et al.*, and column 4, lines 15-25 in *Trescony et al.*). For example, in column 4, lines 15-25, *Trescony et al.* teaches loading polymer matrix with **particulate** inorganic nitrite compounds or nitrite-containing **microspheres**. *Roth et al.* teaches in Examples (columns 15-16) incorporation of DNA, **a large biological molecule**, into the polymeric material for the purpose of gene delivery.

The applicants' composition, on the other hand, forms a complex with NO or NO modulating molecules, and is not dependent on the ability of the polymeric material to entrap nitric oxide or its donors in the pores of the material. Therefore, the use of the applicants' composition does not place limitation on the size or form of the nitric oxide donor. Another advantage of the applicants' macromer composition is that the amount and release kinetics of complexed NO or NO modulating molecules may be varied by altering the chemical structure of the polymer.

In view of the foregoing, applicants respectfully assert that *Roth et al.* and *Trescony et al.*, alone or in combination, fail to teach all the elements of the applicants' invention as claimed in Claims 18 and 20-24. The cited references fail to teach, suggest, or provide motivation to use the applicants' macromer composition as claimed, and do not render the applicants' invention obvious. Applicants respectfully request withdrawal of the rejection.

Information Disclosure Statement

Applicants submit concurrently herewith an Information Disclosure Statement and copies of publications for the Examiner's consideration.

CONCLUSION

The foregoing is submitted as a full and complete response to the non-final Office Action mailed October 3, 2003. Applicants assert that the claims are now in condition for allowance and respectfully request that the application be passed to issuance. If the Examiner believes that any informalities remain in the case, which may be corrected by Examiner's amendment, or that there are any other issues which can be resolved by a telephone interview, a telephone call to the undersigned agent at (404) 815-6102 or to Jamie L. Greene at (404) 745-2473 is respectfully solicited.

The Commissioner is hereby authorized to charge any deficiencies which may be required or credit any overpayment to Deposit Account Number 11-0855.

Respectfully submitted,

Elena S. Polovnikova

By: Elena S. Polovnikova, Ph.D.
Patent Agent
Reg. No.: 52,130

KILPATRICK STOCKTON LLP
Suite 2800, 1100 Peachtree Street
Atlanta, Georgia 30309
(404) 815-6500
Our Docket: 47400-0100 (47400-252658)